Imposed Work of Breathing of Airway Adjuncts

Joseph C. Skinner, Jr., Capt, USAF, SRNA

William D. Gilmer, Capt, USAF, SRNA

Brian A. Molloy, Capt, USAF, SRNA

Gary A. Wells, Capt, USAF, SRNA

Paul N. Austin, Lt Col , USAF, CRNA, PhD

Uniformed Services University of Health Sciences

88th Medical Group

4881 Sugar Maple Dr

Key words: airway adjuncts, imposed work of breathing

Wright-Patterson AFB, OH 45433

937-257-0596

20050111 042

DISTRIBUTION STATEMENT A Approved for Public Release Distribution Unlimited

REPORT DOCUMENTATION PAGE

Form Approved OMB No. 0704-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503.

1. AGENCY USE ONLY (Leave bla	nk) 2. REPORT DAT	E	3. REPORT TYPE AN	D DATES	COVERED
	16.De	c.04		MAJOR	REPORT
4. TITLE AND SUBTITLE			· · · · · · · · · · · · · · · · · · ·		ING NUMBERS
IMPOSED WORK OF BREATH	HING OF AIRWAY	ADJUNCT	S: CO-AUTHORS		
BRIAN A. MOLLOY, WILLIA	M D. GILMER, JOS	SEPH C. SE	KINNER.		
	·				
6. AUTHOR(S)					
CAPT WELLS GARY A II			•		
•	•				
7. PERFORMING ORGANIZATION	NAME(S) AND ADDRE	SS(ES)		8. PERF	ORMING ORGANIZATION
UNIFORMED SERVICES UNI	V OF HEALTH SCI	ENC		REPO	RT NUMBER
· ·					CI04-932
					·
9. SPONSORING/MONITORING A	GENCY NAME(S) AND	ADDRESS(E	S)	10. SPO	NSORING/MONITORING
THE DEPARTMENT OF THE					NCY REPORT NUMBER
AFIT/CIA, BLDG 125					
2950 P STREET					`
				ŀ	
WPAFB OH 45433					
11. SUPPLEMENTARY NOTES				<u> </u>	
THE GOTT ELIMENT AND IN OTE					•
•					,
12a. DISTRIBUTION AVAILABILITY	STATEMENT			112h DIS	TRIBUTION CODE
Unlimited distribution	OTATEMENT			120. 013	THIS HOW CODE
In Accordance With AFI 35-205	C/AFIT Cup 1				·
In Accordance with Art 55-205	7AITI Sup I			·	
•					
13. ABSTRACT (Maximum 200 wo	ordel			<u> </u>	
io. Abortiao i pinaximum 200 wo	103)				
			•		
	•				
					-
·					•
14. SUBJECT TERMS			,		15. NUMBER OF PAGES
·					20
					16. PRICE CODE
17. SECURITY CLASSIFICATION	18. SECURITY CLASS	IFICATION	19. SECURITY CLASSIF	ICATION	20. LIMITATION OF ABSTRACT
OF REPORT	OF THIS PAGE		OF ABSTRACT		
]					1

Abstract

This bench study investigated the imposed work of breathing (WOB_I) of an endotracheal tube (ETT), Laryngeal Mask Airway (LMA®), Streamlined Liner of the Pharyngeal Airway (SLIPA®), and Cobra Perilaryngeal Airway (CobraPLA®). A surrogate measure of imposed work, maximum negative inspiratory pressure (MNIP), was used as the primary measure. Pressure-volume (PV) curves were compared qualitatively.

A spontaneous breathing simulator was used to generate simulated spontaneous breaths. The devices were placed into an intubating manikin modified by connecting the trachea to the simulator. A pneumotachograph was interposed between the airway device and the simulator. Simulated breathing conditions: spontaneously breathing patient receiving one minimum alveolar concentration of isoflurane (Cond 1) and spontaneous breathing of an adult emerging from general anesthesia (Cond 2). MNIP average and SD were calculated for 5 breaths.

For Cond 1, MNIP (cm water) range: -0.6 (SLIPA®) to -2.0 (ETT);

Cond 2, MNIP (cm water) range: -3.1 (SLIPA®) to -7.1 (ETT). ANOVA

indicated statistically significant differences in MNIP for both conditions (p < 0.05). Post hoc tests indicated MNIP differences between all of the devices. PV curves were confirmatory.

Abstract

This bench study investigated the imposed work of breathing (WOB_I) of an endotracheal tube (ETT), Laryngeal Mask Airway (LMA®), Streamlined Liner of the Pharyngeal Airway (SLIPA®), and Cobra Perilaryngeal Airway (CobraPLA®). A surrogate measure of imposed work, maximum negative inspiratory pressure (MNIP), was used as the primary measure. Pressure-volume (PV) curves were compared qualitatively.

A spontaneous breathing simulator was used to generate simulated spontaneous breaths. The devices were placed into an intubating manikin modified by connecting the trachea to the simulator. A pneumotachograph was interposed between the airway device and the simulator. Simulated breathing conditions: spontaneously breathing patient receiving one minimum alveolar concentration of isoflurane (Cond 1) and spontaneous breathing of an adult emerging from general anesthesia (Cond 2). MNIP average and SD were calculated for 5 breaths.

For Cond 1, MNIP (cm water) range: -0.6 (SLIPA®) to -2.0 (ETT);

Cond 2, MNIP (cm water) range: -3.1 (SLIPA®) to -7.1 (ETT). ANOVA

indicated statistically significant differences in MNIP for both conditions (p < 0.05). Post hoc tests indicated MNIP differences between all of the devices. PV curves were confirmatory.

While there were statistically significant differences in WOB_I of the devices, these differences are not likely clinically significant at the simulated inspiratory flow rates except for the WOB_I of the ETT with the patient emerging from anesthesia. Selection should be made on factors including patient status and cost. The findings should aid future developers of these devices.

The views expressed in this abstract are those of the authors and do not reflect the official policy or position of the Uniformed Services University of the Health Sciences, United States Air Force, Department of Defense or the US Government.

Introduction

This study was a quasi-experimental, *in vitro*, bench study that investigated the imposed work of breathing (WOB_I) of an 8.0 mm Endotracheal Tube (ETT), Laryngeal Mask Airway 4 (LMA®), 51mm Streamlined Liner of the Pharyngeal Airway (SLIPA®), and Cobra Perilaryngeal Airway 4 (CobraPLA®). A surrogate of imposed work, maximum negative inspiratory pressure (MNIP), was used as the primary measure. The airway adjuncts tested were placed in a Laerdal Airway Management Trainer. *In situ* the airway device functional characteristics closely resemble *in vivo* placement. Spontaneous breathing was simulated for a 70kg adult and the size of each airway adjunct was based on manufacturers' recommendations for a 70kg

patient. In addition, pressure-volume loops were constructed and compared qualitatively.

Past studies have used single or dual lung models with various breathing simulators. Katz, et al (1985) first simulated spontaneous breathing with a mechanical device while measuring continuous positive airway pressure using a two-chambered lung model. Righini, et al (1997) used a one-lung model when measuring the additional inspiratory resistance imposed by the Laryngeal Mask Airway. Austin, et al (2000) used a two-chambered test lung to measure work of breathing characteristics of portable ventilators. Banner, et al (1994) used a Campbell diagram to determine the WOB₁ when spontaneously breathing through an airway adjunct. Peak negative pressure on a Campbell diagram correlates directly with WOB₁.

A review of the literature for WOB_I shows that there is resistance imposed by any artificial airway. Subsequently, an increase in resistance results in an increased WOB_I and therefore an increased total WOB. All of the studies agreed that change in pressure multiplied by change in volume equated to work of breathing.

The literature supported the fact that there is an increase in WOB_I with airways but results of the studies showed considerable differences. Straus et al (1998) found the WOB of the ETT to be approximately 11% while Haberthur et al (2000) measured the tube related WOB at approximately 52%. Straus et al

used the acoustic reflection method to measure resistance of the ETT and supraglottic airway (1998) while Keidan et al (2000) and Haberthur et al (2000) used traditional flowmeters, esophageal balloons, and tracheal measurements to obtain their data. All of the studies used small sample sizes and the populations varied from pediatric patients to adults. The inclusion criteria for the studies was not clearly stated, nor was the patient's overall health status.

Materials/Methods

For our study a spontaneous breathing simulator was used as in previous investigations examining imposed work (Katz, Kraemer, Gjerde, 1985). A Michigan Instruments Breath Simulation Module (Michigan Instruments, Grand Rapids, MI) was used to generate simulated spontaneous breaths. The breath simulation module was connected to a Michigan Instruments Model 1600 Dual Adult Training Test Lung (Michigan Instruments, Grand Rapids, MI). The training test lung was connected to a Hans Rudolph Research Pneumotachograph (Hans Rudolph, Kansas City, MO). The pneumotachograph was connected interposed between the airway adjunct to be tested and a Laerdal Airway Management Trainer (Laerdal, Stavanger, Norway).

The Michigan Instruments Breath Simulation Module is a device used in conjunction with the training test lung to make a spontaneously breathing lung simulation system. The breath simulator can simulate a spontaneously breathing patient to aid in studying the use of continuous positive airway

pressure, intermittent mandatory ventilation, synchronized intermittent mandatory ventilation, pressure support, or other ventilator modes designed for use with spontaneous breathing patients. It can also be used to test/troubleshoot devices designed to support a spontaneously breathing patient. Finally, it is also used to help assess the added work of breathing associated with airway devices. It can deliver breaths at the rate of 2-30 per minute; inspiratory time 0.5, 1.0, 1.5, and 2.0 seconds; with breath volumes of 50-2000 mL.

The Michigan Instruments Model 1600 Dual Adult Training Test Lung provides a gross simulation of the human pulmonary system. The simulator incorporates two elastomer lung compartments with a typical adult residual capacity. As gas enters the lungs through a simulated airway (breath simulator), the lungs expand vertically. Compliance of both chambers was set at 0.05 L/cm H₂O/second (American Society for Testing and Materials. 1993. F1205-88 Standard specification for anesthesia breathing tubes.).

The Hans Rudolph Research Pneumotach System measures gas flow using the differential-pressure method. As gas flows through the pneumotach, the microprocessor-based system converts the measured differential pressure to a volumetric flow rate. Flow and pressure measurements are used to calculate several ventilatory parameters such as respiratory rate, lung compliance, tidal volume, minute volume, positive end expiratory pressure, etc. Data is obtained by the pneumotach 50 times every second. The data is downloaded directly to a

personal computer and saved as proprietary files that are converted to Excel spreadsheet files (Mircosoft, Redmond, WA).

The airway adjuncts to be tested were placed in a Laerdal Airway Management Trainer. The airway trainer has a lifelike upper torso, head, and airway that allows realistic insertion of airway adjuncts. *In situ* the airway device functional characteristics closely resemble *in vivo* placement. (see figure 1).

The airway adjuncts used in this study were a Mallinckrodt 8.0mm endotracheal tube (Tyco/Mallinckrodt, St. Louis, MO), size 4 CobraPLA® (Engineered Medical Systems, Indianapolis, IN), size 4 LMA® (LMA, North America, San Diego, CA), and 51mm SLIPA® (SLIPAmed UK, Minories, London). The ETT is an airway adjunct that provides a protected (subglottic) airway against aspiration and can be used to administer positive pressure ventilation. The LMA® is a supraglottic airway adjunct that is an alternative to the facemask for achieving and maintaining control of an airway although it is not a protected airway. The SLIPA® is a new supraglottic airway that is an alternative to the face mask or LMA®. It is currently used in England and it will be distributed in the U.S. by Hudson-RCI sometime in 2004 (Miller, D. M. Dept of Anaesthetics, Guy's Hospital, London). The CobraPLA® is designed to be positioned in the hypopharynx where it abuts the structure of the laryngeal

inlet. The distal end of the CobraPLA® holds both the soft tissue and the epiglottis out of the way, facilitating ventilation through the slotted openings.

The airway adjuncts were tested using two simulated breathing conditions. The first simulated a spontaneously breathing patient receiving one minimum alveolar concentration (MAC) of a volatile anesthetic: tidal volume 0.2 L with inspiratory flow of 26 L/min (Fourcade, Stevens, Larson, Cromwell, Bahlman, Hickey, Halsey, Eger, 1971). The second simulated the spontaneous breathing of an adult emerging from general anesthesia: tidal volume 0.8 L with inspiratory flow of 60 L/min: (Fourcade, et al, 1971).

This study used a mechanical model of spontaneous breathing and there was not a sample of subjects as in human studies. The airway adjuncts to be tested were obtained from the stock at a major medical center (ETT and LMA®). The SLIPA® was obtained from Donald Miller, MB ChB, PhD, GKT, Department of Anaesthetics, NGH2, Guy's Hospital, London, SEI 9RT. The CobraPLA® was obtained from a national distributor, Tri-Anim Inc., in coordination with the manufacturer, Engineered Medical Systems. Spontaneous breathing was simulated for a 70 kg adult and the size of each airway adjunct was based on the manufacturers' recommendation for a 70 kg patient. The Laerdal Airway Trainer® is an approximation of a 70 kilogram adult male's anatomical features. The sample consisted of one size 4 LMA®,

one size 4 CobraPLA®, one 8.0 mm internal diameter endotracheal tube, and one 51mm SLIPA®.

Due to the difficulty with directly measuring WOB_I and the cost of the measurement equipment, the investigation used two principle surrogates of imposed work. The first was maximum negative inspiratory pressure, as was used in an earlier study examining WOB_I. The more negative the maximum negative airway pressure, the more work is imposed by the airway adjunct (Katz, Kraemer, Gjerde, 1985). The second principle surrogate of imposed work was a qualitative examination of pressure-volume curves constructed with measurements from measurements obtained with each airway adjunct. This offered a qualitative assessment of imposed work of breathing (Austin, Campbell, Johannigman, Branson, 2001). For each condition, data was collected from five consecutive breaths. Data reported includes the average and standard deviations of the following: tidal volume, peak inspiratory flow, and maximum negative inspiratory pressure.

Before samples were tested and recorded for the research, repeated measures under test conditions were ran to ensure that recordings were reproducible. Minimally accepted values for reliability comparisons were accepted for coefficients of 0.7 not because the instrument is new but rather there are no specific studies reporting its use. Having one operator perform the tests helped ensure intra-rater reliability. These re-test measurements were

performed before each research test measurement and compared for precision.

Any result that did not meet the accepted coefficient was discarded and the test was performed again. A spreadsheet was generated for review to ensure reproducibility under identical conditions.

The complete setup was calibrated before each device was measured using the manufacturers recommendations. The pneumotach has specific manufacturer calibrations that were followed for initial setup before measurements for the study were conducted. In addition, pressure measurements were assessed utilizing a U-tube manometer before each test was conducted for the study. Flow accuracy was tested utilizing a three-liter super syringe before and after each measurement. These measurements determined if error was present within the instrument. Photos taken through a fiberoptic bronchoscope documented correct placement of the airway adjuncts. Local nurse anesthesia faculty approved the protocol and was present during data collection; thus helping to insure validity during the study design and data collection phases. Direct downloading of data from the breathing system monitor to the computer also enhanced accuracy and precision.

Only one operator and measuring device was used to ensure consistency. Pressure and volume readings were repeatedly measured prior to measurements with an airway adjunct to limit variability. Airway adjunct

placement was verified via fiberoptic bronchoscope prior to measuring pressure-volume loops with the device in the airway management trainer.

This study did not include human subjects and as such was not subject to formal consent procedures. IRB approval was sought with the IRB reporting the study was exempt from IRB approval.

Results

Analysis of variance (ANOVA) for repeated measures compared the tidal volume, peak inspiratory flow, and maximum negative inspiratory pressure of the airway adjuncts for each breathing condition. The level of significance was set at p < or = 0.05. Data analysis was facilitated by the use of SPSS-X (SPSS Inc., Chicago, IL). The maximum negative inspiratory pressure, tidal volume, and peak inspiratory flow for the various devices at 26LPM and 60LPM are listed in figure 2. ANOVA tests utilizing SPSS were ran on the maximum negative inspiratory pressure using the airway manikin without a device as a control. ANOVA was statistically significant, p < .05, for MNIP at 26 L/min with the ETT, LMA®, SLIPA®, and CobraPLA® compared to no device. ANOVA was statistically significant, p < .05 for MNIP at 60 L/min with the ETT, LMA®, SLIPA®, and CobraPLA® compared to no device. Post hoc tests showed no significant difference between the SLIPA and the control (p > 0.05). However, significant differences were found between the other devices (p < 0.05).

Pressure volume loops were plotted and overlaid for qualitative comparison, see figure 3 and 4.

Discussion

Qualitative analysis of the pressure-volume loops shows a noticeable difference between the maximum negative inspiratory pressure of the devices. This can partially be explained by Pousielle's Law that states that resistance varies directly with tube length and inversely to the fourth power with tube radius. All of the devices are substantially shorter than the endotracheal tube, and, excluding the 15 mm connector, substantially larger in diameter. Our study showed that the maximum negative inspiratory pressure was proportional to device length. The SLIPA® was no different than the control at 26LPM and only slightly different at 60LPM. The LMA®, CobraPLA®, and ETT followed a pattern with resistance increasing as the devices got longer, with one exception. The LMA® is approximately one centimeter longer than the CobraPLA® but it had slightly less resistance than the CobraPLA®. The CobraPLA® has a larger diameter tube and is slightly shorter than the LMA®, yet it has more resistance. This might be explained by an acute angle at the distal tip of the CobraPLA® which could increase resistance.

Qualitative analysis of the tidal volumes demonstrated that as the negative inspiratory pressure became more negative the tidal volume decreased. Hence, the control without a device in place had the largest tidal volume and the ETT had the lowest tidal volume.

As expected, qualitative analysis revealed no differences in flow between devices at the different flow rates.

It is inherent to anesthesia providers that insertion of a device into the airway will impose a burden on the spontaneously breathing patient. The impetus for this study was to determine if there was a significant difference in the imposed work of breathing between airway devices *in vitro*. It is apparent that there are significant differences in the WOB_I of the different airway devices tested.

The differences obtained in this study might be most relevant to those patients who have compromised respiratory status; the extremes of age, or chronic/acute respiratory impairment. The data obtained could be used to determine which device to use for a given patient.

It is duly noted that secretions and other physical characteristics can alter or affect WOB. The results of this *in vitro* study could be used as a guide to select airway devices for different patient populations. However, further studies are recommended to determine if these results correlate to conditions found *in vivo*. Our results may not be transferable to pediatric devices so

further studies could be done to compare findings on new pediatric airway adjuncts.

The views expressed in this paper are those of the authors and do not reflect the official policy or position of the Uniformed Services University of the Health Sciences, United States Air Force, Department of Defense or the US Government.

Acknowledgements

Donald Miller, MB ChB, PhD, GKT, Department of Anaesthetics, NGH2, Guy's Hospital, London, SEI 9RT. SLIPA®

Tri-Anim Inc., CobraPLA®

Paul N. Austin, Lt Col, USAF, CRNA, PhD

Dr. Janice Agazio

Dr. Eugene Levine

References

American Society for Testing and Materials. (1993). <u>F1205-88 Standard</u> specification for anesthesia breathing tubes.

Austin, P.N., Campbell, R.S., Johanningmam, J.A., and Branson, R.D. (2000). Work of breathing characteristics of seven portable ventilators.

Resuscitation, 49 (2), 159-167.

Banner, M. J., Jaeger, M. J., & Kirby, R. R. (1994). Components of the work of breathing and implications for monitoring ventilator-dependent patients. <u>Critical Care Medicine</u>, 22, 515-523

Fourcade H.E., Stevens, W.C., Larson, C.P., Cromwell, T.H., Bahlman, S.H., Hickey, R.F., Halsey, M.J., Eger, E.I. (1971). The ventilatory effects of forane, a new inhaled anesthetic. Anesthesiology, 35 (1), 26-31.

Haberthur, C, Elsasser, S., Eberhard, L., Stocker, R., Guttmann, J. (2000). Total versus tube-related work of breathing in ventilator-dependent patients.

<u>Acta Anaesthesiologica Scandanavia</u>, 44, 749.

Hans Rudolph Pneumotach. Instruction manual for the Hans Rudolph Pneumotach. Kansas City, MO. 2001.

Katz, J.A., Kraemer, R.W., Gjerde, G.E. (1985). Inspiratory work and airway pressure with continuous positive airway pressure delivery systems.

Chest, 88, 519-36.

Keidan, I., Fine, G., Kagawa, T, Schneck, F., Motoyama, E. (2000). Work of breathing during spontaneous ventilation in anesthetized children: A comparative study among the face mask, laryngeal mask airway and endotracheal tube. <u>Anesthesia & Analgesia</u>, 91, 1381-1388.

Michigan Instruments Breath Simulation Module. Instruction manual for the breath simulation module. Grand Rapids, MI. 2001.

Michigan Instruments Test Training Lung. Instruction manual for the 1600 TTL. Grand Rapids, MI. 2001.

Righini, E. R., Marangoni, E., Volta, C. A., Alvisi, R., Bortolazzi, S., Gritti, vvG. (1997). Additional inspiratory resistance imposed by the laryngeal mask airway: *in vitro* versus *in vivo* comparison. <u>Anaesthesia</u>, 52, 872-878

Straus, C., Louis, B., Isabey, D., Lemaire, F., Harf, A., Brochard, L. (1998).

Contribution of the endotracheal tube and the upper airway to breathing workload. American Journal of Respiratory and Critical Care Medicine, 157, 23-30.

Figures

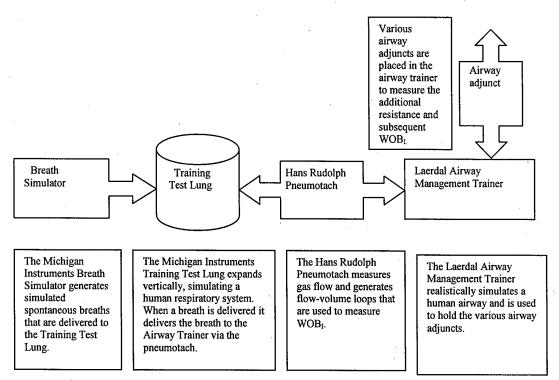


Figure 1

Maximum Negative Inspiratory Pressure 26 L/min Flow

Breath	1	2	3	4	5	Mean	SD
8 ETT	-2	-2	-2	-2	-2	-2	0
4 LMA®	-1	-1	-1	-1	-1	-1	0
51 SLIPA®	-0.6	-0.6	-0.6	-0.6	-0.6	-0.6	.0
4 CobraPLA®	-1.2	-1.2	-1.2	-1.2	-1.2	-1.2	0
Control	-0.6	-0.6	-0.6	-0.6	-0.6	-0.6	0

Maximum Negative Inspiratory Pressure 60 L/min Flow

Breath	1	2	3	4	5	Mean	SD
8 ETT	-7	-7.2	-7.1	-7.2	-7	-7.1	0.1
4 LMA®	-4.3	-4.3	-4.3	-4.3	-4.3	-4.3	0
51 SLIPA®	-3.1	-3.1	-3.1	-3.1	-3.1	-3.1	0
4 CobraPLA®	-4.7	-4.7	-4.7	-4.7	-4.7	-4.7	0
Control	-2.1	-2.1	-2.1	-2.1	-2.1	-2.1	0

Tidal Volume 26 L/min Flow

Breath	1	2	3	4	5	Mean	SD
8 ETT	154.6	160	173.7	159.8	153.6	160.3	8
4 LMA®	176.3	176.3	176.6	176.6	177	176.6	0.3
51 SLIPA®	178.7	174.8	175.8	176.8	177.7	176.8	1.5
4 CobraPLA®	162.1	174.1	170.5	173.3	174.2	170.8	5.1
Control	186.5	192.3	187.2	191.8	187	189	2.8

Tidal Volume 60 L/min Flow

Breath	1	2	3	4	5	Mean	SD
8 ETT	650.1	692.1	754.3	714.9	756.1	713.5	44.6
4 LMA®	807.8	789.9	813	793.8	796.1	800.1	9.8
51 SLIPA®	824.9	826.6	806.3	808.4	808.4	814.9	9.9
4 CobraPLA®	819.1	821.6	804.8	805.3	809.3	812	7.9
Control	843	832.7	840.9	850.1	838.2	841	6.4

Peak Inspiratory Flow 26 L/min Flow

Breath	1	2	3	4	5	Mean	SD
8 ETT	29.4	29.6	29.4	29.4	29.4	29.4	0.09
4 LMA®	28.6	28.8	28.8	28.8	28.8	28.8	0.09
51 SLIPA®	28.6	28.6	28.6	28.6	28.6	28.6	0
4 CobraPLA®	30.8	30.6	30.3	30.3	30.5	30.5	0.2
Control	29.8	29.8	29.8	29.8	29.8	29.8	0

Peak Inspiratory Flow 60 L/min Flow

Breath	1	2	3	4	5	Mean	SD
8 ETT	60	60	60.1	60.1	60.1	60.1	0.05
4 LMA®	60.7	60.7	60.6	60.6	61	60.7	0.16
51 SLIPA®	61.2	61.2	60.8	61.2	61.2	61.1	0.18
4 CobraPLA®	61	61	61	61	61.3	61.1	0.13
Control	59.3	59.5	59.6	58.9	59.2	59.3	0.27

Figure 2

26 LPM Pressure Volume Loops

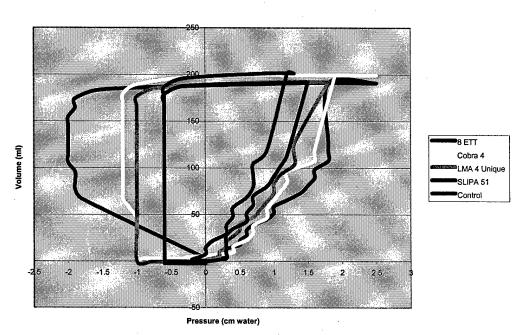


Figure 3

60 LPM Pressure Volume Loop:

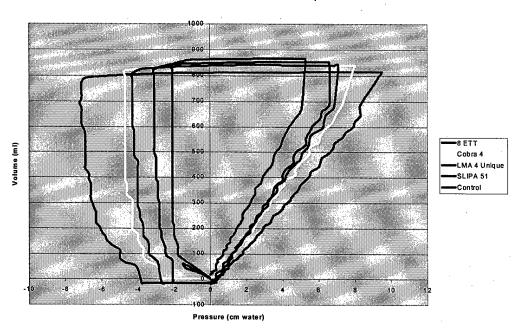


Figure 4